Form 4

Application for a Recognised Ethics Committee (REC) Opinion on a Substantial Amendment to a Clinical Trial on a Medicinal Product for Human Use.

(This application form should be completed by the Sponsor and submitted via the central allocation system. It should be filled out in language comprehensible to a lay person.)

A. TRIAL IDENTIFICATION

A.1	
EudraCT no.:	
Title of clinical trial:	
REC reference no:	
Amendment no:	
Submission date:	

A.2 Please indicate whether this is: *(tick as appropriate)*	
An application for a substantial amendment	☐
A modified application for a substantial amendment	☐

B. APPLICANT IDENTIFICATION

B.1 Sponsor	
Name:	
Organisation:	
Address:	
Tel:	
Fax:	
E-mail:	

C. AMENDMENT IDENTIFICATION

C.1	**Amendment to Protocol**	☐ **Yes** ☐ **No**
	(If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.)	

C.2	**Amendment to initial request for an ethical opinion**	☐ **Yes** ☐ **No**
	If yes, please refer to relevant sections of the main application form.	

C.3	**Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the clinical trial**	☐ **Yes** ☐ **No**
	If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.	

C.4	**Other**	☐ **Yes** ☐ **No**
	If Yes, please specify	

D. DETAILS OF AMENDMENT

D.1	**Give a description of the amendments being proposed including the reasons for making such amendments**

D.2	**Checklist of Documents to be submitted with this application form** *(Tick as appropriate)*	
	• Covering Letter on Headed paper, including list of modified documentation with new version numbers and dates.	☐
	• Revised Protocol with new version number and date with amended data highlighted	☐
	• Revised information sheets and consent forms with new version number and dates and amended data highlighted	☐
	• Other supporting documentation	☐

DECLARATION OF SPONSOR

This declaration should be signed before the application will be considered valid by the REC.

- I confirm that the information contained in this form is accurate to the best of my knowledge and I take full responsibility for it.

- I consider that it would be reasonable for the proposed amendment to be implemented.

- I undertake to abide by the ethical principles outlined in the Declaration of Helsinki, and the International Conference on Harmonisation's Good Clinical Practice Guidelines (ICH GCP) and the European Communities (Clinical Trials on Medicinal Products for Human Use) regulations, 2004 (S.I. No 190 of 2004).

Signature of Sponsor: _____

Print Name: _____

Date of submission: _____ (dd/mm/yyyy)